DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 21, 2014

Modern Medical Equipment Manufacturing Limited
Mr. Thomas Chan Tsz Fung
Regulatory Supervisor
35-41 Tai Lin Pai Road, Unit F
5th Floor, Gold King Ind. Building
Kwai Chung, N.T.
Hong Kong, China

Re: K134006
Trade/Device Name: Disposable Laparascopic Electrode
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 20, 2014
Received: October 27, 2014

Dear Mr. Chan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K134006

Device Name
Disposable Laparoscopic Electrode

Indications for Use *(Describe)*
The electrode is used to cut and coagulate the selected tissue for laparoscopic procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1. 510(k) Owner

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Contact person: Thomas, Chan Tsz Fung

Date of preparation: Oct 20 2014

2. Device

Name of Device:	Disposable Laparoscopic electrode
Trade or proprietary name:	Disposable Laparoscopic electrode
Common or usual name:	Disposable Laparoscopic electrode
Classification name:	Electrosurgical, Cutting & Coagulation & Accessories
Classification Panel:	General & Plastic Surgery
Product Code:	GEI
Class:	II

3. Device description

Disposable Laparoscopic Electrode consists of a conductive electrode tip, an insulated shaft and a conductive post. The electrode tip is either coated or non-coated and the conductive post is either 2.36mm or 4mm. The conductive post is inserted into the electrode entry of electrosurgical pencil from which it receives the high frequency current and delivers the current onto a target tissue for cutting and coagulation in laparoscopic procedure. During the operation, the electrode tip and the insulated shaft are to be inserted through a 5mm trocar. This device is used in conjunction with a compatible electrosurgical generator and patient grounding pad and complies with IEC60601-1 and IEC60601-2-2.

4. Intended use

The electrode is used to cut and coagulate the selected tissue for laparoscopic procedures.

5. Predicate device

Megadyne E-Z Clean Disposable Laparoscopic Electrodes (K913281)

Modern Medical Equipment Mfg. Ltd. - Laparoscopic Instrument, Electrode and Cable (K032965)

6. Technological characteristic

The proposed disposable laparoscopic electrode consists of a conductive electrode tip, an insulated shaft and a conductive post. The electrode tip is either coated or coated or non-coated stainless steel. The coated electrode eliminated the needs of using tip polisher to remove the eschar. The diameter of the conductive post is available in 1.6mm or 2.36mm.The conductive electrode tip is the conductive portion of the electrode which has 11 tip styles, delivers high frequency current onto a target tissue for cutting and/or coagulation during an electro-surgery. The insulated shaft is the mid portion of the electrode. It is insulated with non-conductive material to prevent accidental conduction of the electrosurgical current from this point to the patient. The conductive post is used to plug the electrode into the nose of an electrosurgical pencil from which it receives the electrical current.

The construction of proposed electrode and the predicted device is identical although the only differences are the coating of electrode tip and the diameter of conductive post. The predicate device only is available one type of tip finishing: coated or non-coated stainless steel and its conductive post is only 2.36mm. However, these differences are not significantly to change mechanism of operation. There are no new questions raised regarding to effectiveness and safety.

7. Substantial Equivalence

The technological characteristic in both proposed device and predicate device is identical. Moreover, performance testing data show that operation result by using posed device and predicate device shall be the same.

8. Performance Testing Data

Validation and Verification testing was performed on the device and packaging.

Simulation Tests include comparative testing was performed on porcine kidney, liver, and muscle for both Cut and Coagulation modes at 30W, 50W, and 100W output power. It demonstrates that the performance of device operation and result of eschar buildup on the tip of electrode are no significant difference between proposed device and predicate device.

9. Safety and Biocompatibility testing data

Testing was performed to comply with
IEC60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007)
IEC60601-2-2: 2009 (Fifth Ed)

EO and ECH residue test was performed in accordance to ISO10993-7 Biological

evaluation of medical devices-Part 7: Ethylene oxide sterilization residualsafter ETO sterilization to demonstrate no residue on the patient contact portion of device after aeration.

The following Biocompatibility tests were performed in accordance to ISO10993-1 Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process

- Intracutaneous Reactivity Test
- In vitro Cytotoxicity Test
- Acute Systemic Toxicity Test
- Skin sensitization tests
- In Vitro Hemolysis Study

10. Conclusion

Based on comparing technological characteristic and performance testing data, we believe the proposed device, disposable laparoscopic electrode is substantial equivalence to predicate device.